



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,455	01/14/2005	Helmut Goldmann	26569U	8794
20529	7590	02/12/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER SCHILLINGER, ANN M	
			ART UNIT 3738	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/521,455

Applicant(s)

GOLDMANN, HELMUT

Examiner

Ann Schillinger

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 4/13/2005.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 21, 22, 25-27, and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Trogolo et al. (U.S. Pat. No. 6,296,863). Trogolo et al. discloses the following of claim 18: prosthesis for replacement of hollow organs with antibiotic long-term action with a basic structure which defines the form of the prosthesis and which is made of substantially non-absorbable or only slowly absorbable polymer material (10, 18; col. 3, lines 2-4, 15-21) and of a coating of an absorbable material (col. 8, lines 31-40), with a layer of metallic silver (20; col. 3, lines 66 through col. 4, lines 30) situated on the polymer material and underneath the coating (col. 8, lines 9-22, 31-40 indicates that the collagen coating disclosed above is added last over the base and the silver layer).

Trogolo et al. discloses the following of claim 19: the prosthesis as claimed in claim 18, wherein the silver layer adheres firmly on the polymer material (col. 3, lines 63-65).

Trogolo et al. discloses the following of claim 21: the prosthesis as claimed in claim 18, wherein silver atoms of the silver layer are impressed into the polymer surface of the basic structure (col. 6, lines 1-7).

Trogolo et al. discloses the following of claim 22: the prosthesis as claimed in claim 18, wherein the silver layer is a substantially closed layer (see Figure 4).

Trogolo et al. discloses the following of claim 25: the prosthesis as claimed in claim 18, wherein the silver layer is composed exclusively of elemental silver (col. 6, lines 1-7).

Trogolo et al. discloses the following of claim 26: the prosthesis as claimed in claim 18, wherein the basic structure is porous (col. 2, lines 65 through col. 3, lines 2), the silver layer leaves the pores open (col. 8, lines 18-20), and the absorbable layer is an impregnation which seals the pores of the prosthesis (col. 8, lines 31-33 as col. 2, lines 56-59 indicates that leaving the prosthesis uncoated maintains the base material's porous property).

Trogolo et al. discloses the following of claim 27: the prosthesis as claimed in claim 18, wherein the absorbable coating is formed from optionally crosslinked biological material (col. 8, lines 31-33).

Trogolo et al. discloses the following of claim 31: the prosthesis as claimed in claim 18, wherein the basic structure is made from a textile material (col. 3, lines 5-6).

Trogolo et al. discloses the following of claim 32: the prosthesis as claimed in claim 31, wherein the fibers of the textile basic structure are coated with silver at least at the locations which point toward at least one surface of the prosthesis (see Figure 4).

Trogolo et al. discloses the following of claim 33: the prosthesis as claimed in claim 32, wherein substantially the entire surface of the fibers being coated with silver (see Figure 4).

Trogolo et al. discloses the following of claim 34: the prosthesis as claimed in claim 18, wherein the basic structure is made from a sintered material (col. 3, lines 2-4).

Trogolo et al. discloses the following of claim 35: the prosthesis as claimed in claim 18, wherein said implant is designed as a vascular prosthesis (col. 1, lines 5-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Burrell et al. (U. S. Pat. No. 5,837,275). Trogolo et al. does not disclose how the silver layer is placed on the implant. Burrell et al. teaches in the abstract that anti-microbial coatings, such as a silver, may be administered by vapor deposition because this technique produces atomic disorder in the coating such that sustained release of metal ions sufficient to produce an anti-microbial effect is achieved. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use vapor deposition to form the silver coating so that the silver coating will have an anti-microbial effect on the medical device it is applied to.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Pourrezai et al. (U. S. Pat. No. 5,685,961). Trogolo et al. does not disclose choosing the thickness of the silver layer coating so that it will be break down in the body over a desired period of time. Pourrezai et al. teaches in col. 7, lines 33-39 that the relative decomposition rate of silver is known, therefore the thickness of the silver layer may be calculated according to how long a particular patient will need the medical device to be implanted. Therefore, it would have

Art Unit: 3738

been obvious to one of ordinary skill in the art at the time the invention was made to make the silver layer thick enough to last for the necessary period of time with the decomposition rate of the silver coatings being known. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create a silver layer that breaks down 5 to 10% of the layer per annum, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Lawson et al. (U. S. Pat. No. 6,579,539). Trogolo et al. does not disclose the silver layer's thickness. Lawson et al. in col. 3, lines 2-10 teaches the range thicknesses available to a silver layer which can be chosen to best cover the base material based on weight per unit area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the disclosed thickness ranges as is best for a silver layer to adequately cover the given base material.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Shikani et al. (U. S. Pat. No. 5,762,638). Trogolo et al. does not disclose using a synthetic polymers as the absorbable coating on the outside of the prosthesis. Shikani et al. teaches in col. 14, lines 8-25, 37-47 that synthetic polymers and co-polymers make excellent coating materials on prosthetic devices because they are not prone to swelling and are non bioerodible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to potentially replace Trogolo et al.'s collagen coating with a synthetic

Art Unit: 3738

polymer as both are known in the art to have properties that are necessary for coatings on prosthetics.

Regarding claims 29 and 30, Shikani et al. teaches in col. 5, lines 47-62 that it is known in the art to place drugs in the outer coating of a device such that it can be programmed to be released after a certain period of time based on the choice of the outer coating. This will help prevent inflammation and granulation tissue at the sites where these prosthetics are implanted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use such an outer coating on Trogolo et al.'s prosthesis to prevent inflammation and granulation tissue at the site of implantation. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to chose a coating that is absorbed after four months at the latest, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
January 24, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER